

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING,
SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

Bentley v. Pfizer, Inc., et al.,

CA No. 05-11997-PBS

Bulger v. Pfizer, Inc., et al.,

CA No. 07-11426-PBS

Dixon v. Pfizer, Inc., et al.,

CA No. 05-11998-PBS

McGee v. Pfizer, Inc., et al.,

CA No. 05-12593-PBS

Owens v. Pfizer, Inc., et al.,

CA No. 05-11017-PBS

Pursey v. Pfizer, Inc., et al.,

CA No. 07-10106-PBS

Roberson v. Pfizer, Inc., et al.,

CA No. 05-12001-PBS

Shearer v. Pfizer, Inc., et al.,

CA No. 07-11428-PBS

Smith v. Pfizer, Inc., et al.,

CA No 05-11515-PBS

Valentine v. Pfizer, Inc., et al.,

CA No. 07-11067-PBS

Vercillo v. Pfizer, Inc., et al.,

CA No. 05-11019-PBS

Woolum v. Pfizer, Inc., et al.,

CA No. 07-10853-PBS

) MDL Docket No. 1629

) Master File No. 04-10981

) Judge Patti B. Saris

) Magistrate Judge Leo T.
) Sorokin

MEMORANDUM AND ORDER

May 26, 2009

Saris, U.S.D.J.

I. INTRODUCTION

This multi-district litigation involves over 100 plaintiffs who allege they, or their decedents, suffered suicide-related injuries after their doctors prescribed the drug Neurontin, manufactured by defendants Pfizer Inc. and Warner-Lambert Company LLC (collectively "Pfizer"). Plaintiffs allege that defendants engaged in a fraudulent scheme to market Neurontin for "off-label" uses not approved by the Food and Drug Administration (FDA). Among other things, they allege that defendants' employees and sales representatives fraudulently misrepresented Neurontin's safety and effectiveness for off-label usage and failed to disclose studies indicating that Neurontin can cause behavioral disturbances, depression, and suicidal actions.¹

Pfizer has moved to dismiss the fraud claims pursuant to Fed. R. Civ. P. 9(b) and Fed. R. Civ. P. 12(b)(6) on the ground that plaintiffs failed to allege that prescribing physicians actually received and relied on any fraudulent misrepresentations or omissions made during the course of improper off-label marketing.

As background, this is the second round of motions to dismiss. In 2006, the Court ruled that the original complaints were "clearly deficient" because they failed to allege that any

¹ Plaintiffs each allege five causes of action: (1) negligence, (2) breach of warranty, (3) strict liability, (4) fraud and (5) violations of state consumer protection laws.

of plaintiffs' physicians met with a Pfizer liaison, attended a conference, or otherwise received the material misrepresentation upon which she then relied. In re Neurontin Mktg. and Sales Practicing Litig., No. 04-10981, 2007 WL 609875, at *2 (D. Mass. Feb. 23, 2007). However, because the information was exclusively within the control of the pharmaceutical companies and the doctors, the Court allowed plaintiffs the opportunity for additional discovery in fourteen "pilot" cases. The discovery was with respect to contacts between Pfizer's sales team and the doctors who prescribed the medication, including the ability to depose the doctors and evaluate relevant sales documentation. On April 7, 2008, based on this discovery,² the plaintiffs in twelve of the fourteen "pilot" cases filed amended complaints (Docket Nos. 1201-12) which are the subject of these renewed motions to dismiss.

After the hearing and a review of the briefs, the Court **ALLOWS in part** and **DENIES in part** the defendants' motions to dismiss.

II. FACTUAL BACKGROUND

Each of the pilot plaintiffs' amended complaints raise virtually identical claims regarding the off-label marketing campaign and the alleged fraudulent misrepresentations regarding

² The parties deposed twenty-five prescribing physicians and twelve Pfizer territory representatives.

the safety and efficacy of Neurontin. When all reasonable inferences are drawn in favor of the non-moving parties, the amended complaints allege the following facts, many of which defendants dispute.

A. FDA Approval of Neurontin for Epilepsy

Parke-Davis is a division of Warner-Lambert Company which is now owned by Pfizer. On January 15, 1992, Parke-Davis submitted a New Drug Application ("NDA") to the FDA seeking approval for Neurontin as an adjunctive therapy for epilepsy. As part of its submission, Parke-Davis submitted data documenting adverse events reported in its clinical trials. For example, seventy-eight individuals, or 5.3 percent of the total exposed patient population of the NDA, reported depression as an adverse event. Seven instances of depression were categorized as "serious" events, and nine patients withdrew from studies because of depression. There were also numerous mood and behavioral disturbances, or "psychobiologic" adverse events, reported in the studies. In the FDA review of the data, an FDA medical reviewer, Dr. Cynthia McCormick, M.D., raised concerns about the relationship between Neurontin and the adverse events of depression and suicide:

Less common but more serious events may limit the drug's widespread usefulness. . . .
[D]epression, while it may not be an infrequent occurrence in the epileptic population, may become worse and require

intervention or lead to suicide, as it has resulted in suicide attempts.

The FDA concluded its review of Neurontin's NDA by stating that Neurontin was "approvable with appropriate and prominent labeling for use in a specific population."

On or about December 15, 1992, the Peripheral and Central Nervous System Drugs Advisory Committee to the Department of Health and Human Services voted to recommend Neurontin for a very specific use in a limited population, the adjunctive treatment for refractory epilepsy. Approximately one year later, on December 30, 1993, the company received FDA approval to market Neurontin for the adjunctive treatment of epilepsy in adults.³ The FDA stated that the drug is only effective at 900 to 1800 milligrams per day.

B. Illegal Off-Label Marketing Campaign

Beginning in 1995, defendants engaged in a multi-faceted marketing campaign designed to increase off-label sales of Neurontin. Defendants began to illegally market and promote the sale of Neurontin for "off-label uses" which were not approved by the FDA, such as the treatment of pain, bipolar disorder and anxiety. Product liability plaintiffs allege the national

³ In May 2002, the FDA approved Neurontin for the management of post-herpetic neuralgia (pain resulting from nerve damage caused by shingles or herpes zoster) in adults. In re Neurontin Mktg. and Sale Practices Litig., 244 F.R.D. 89, 92 (D. Mass. 2007).

campaign included: a) sales representatives detailing Neurontin to prescribing physicians for uses and at higher dosages than had been tested or approved; b) funded presentations by consultants and liaisons to encourage word-of-mouth recommendations for off-label uses within the medical community; c) increased clinical testing and development for new off-label usages; and d) affirmative promotional statements intended to conceal or misrepresent negative or contradictory data on the drug's safety or efficacy for off-label uses.

In 1995, sales representatives made presentations in details to doctors' offices⁴ promoting Neurontin for pain and for reflex sympathetic dystrophy, a nerve damage syndrome. Defendants trained their sales representatives to promote off-label uses and motivated sales representatives to encourage prescription amounts for dosages higher than approved by the FDA.

Defendants made a concerted effort to disperse "word-of-mouth" recommendations throughout the medical community. Defendants hired physician consultants, provided them with payments or honorariums, and arranged promotional junkets and conferences in resorts for doctors (and their spouses) where the

⁴"'Detailing' is the one-on-one promotion of drugs to physicians by pharmaceutical sales representatives, usually through regular office visits, free gifts, and friendly advice, when 'drug reps go to doctors' offices to describe the benefits of a specific drug.'" In re Zyprexa Prod. Liab. Litig., No. 04-1596, 2008 WL 2696916, at *32 (E.D.N.Y. July 2, 2008) (quoting Daniel Carlat, Dr. Drug Rep., N.Y. Times. Mag., Nov. 25, 2007, at 67).

consultants gave presentations on off-label uses of Neurontin. Employees of the defendants' Medical and Scientific Affairs Department, whom defendants referred to as "medical liaisons," made presentations to doctors with company slides that promoted off-label usages of Neurontin for a variety of conditions including migraines, post-herpetic neuralgia, restless leg syndrome, bipolar disorder, and amyotrophic lateral sclerosis (also know as "ALS" or "Lou Gehrig's Disease"). Medical liaisons also falsely informed doctors that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder, peripheral and diabetic neuropathy, and other pain syndromes, indicated 90% response rates.

While defendants were promoting Neurontin's efficacy for off-label uses, Pfizer was actively researching alternative uses for the drug. Defendants had a Drug Development Team and New Product Committee whose stated purpose was to explore new uses for Neurontin beyond the epileptic population. Defendants also sought approval from the FDA for additional uses. Defendants' application to the FDA for approval of Neurontin as a monotherapy for partial seizures was denied on August 26, 1997. The FDA also refused to increase the approved dosage of Neurontin to amounts greater than 1800 mg per day.

Clinical evidence emerged from the FDA trials and afterwards that did not support Pfizer's promotion of Neurontin as safe and effective for off-label uses. Defendants and their

representatives nonetheless promoted off-label uses even where there was contradictory clinical evidence. For example, defendants sponsored a study conducted at the Harvard Bipolar Research Program in 1998, which concluded that patients receiving Neurontin did worse than those patients on placebo sugar pills. Although defendants were aware of the results of this study, they did not publish the study's results until 2000, after a significant number of physicians were induced to prescribe Neurontin.

In their national marketing campaign, defendants failed to disclose or warn that Neurontin may be associated with psychobiologic events including depression and suicidality. Indeed, Pfizer representatives strategically compared Neurontin with competing drugs which already had a specific warning related to suicide. On January 16, 2003, defendants' Senior Medical Director, Dr. Catherine Clarey, flatly denied any association between Neurontin and depression or suicidality when, on National Public Radio ("NPR"), she stated, "[T]here is absolutely no evidence that Neurontin . . . with all these prescriptions that it has been associated with suicidal behavior or that it can cause suicidal behavior."

Pfizer's marketing campaign for Neurontin correlates with a substantial rise in Neurontin sales. Sales of Neurontin for non-FDA approved uses have skyrocketed steadily since 1998. From 2000 to the present, off-label usage constitutes 93 to 94 percent

of all Neurontin sales. This sharply contrasts with sales for approved uses where sales have declined during the relevant period.

C. Convicted

Defendant Warner-Lambert Company LLC was charged in the United States District Court for the District of Massachusetts with improper off-label marketing in violation of 21 U.S.C. §§ 331(a), 331(d), 333(a)(2), 352(f)(1) and 355(a), and pled guilty to the charges on June 7, 2004. This multi-district litigation followed.

D. Specific Complaints

1. No Direct Contacts between Pfizer and Prescribing Provider

All the of the plaintiffs' amended complaints seek to recover damages based on injuries related to suicide or attempted suicide, which plaintiffs claim was caused by Neurontin, prescribed off-label for indications not approved by the FDA. Seven of the complaints fail to allege any specific contact between Pfizer and the prescribing provider.

- Pamela Woolum, a citizen of Florida, suffered from anxiety. Peter Lautenbach, an Osteopath, and her healthcare provider Dr. Peter Ramirez, prescribed Neurontin, and on October 31, 2003, she attempted suicide. (Docket No. 1201.)
- Pearlle Faye McGee, a citizen of Texas, suffered from fibromyalgia. Her prescriber Dr. Constantine Saadeh prescribed Neurontin,

and on May 25, 2001, she committed suicide.
(Docket No. 1202.)

- Frank Vercillo, a resident of New York, suffered from anxiety and depression. His psychiatrist Dr. Thomas Maltese prescribed Neurontin, and on November 30, 2001, he attempted suicide. (Docket No. 1203.)

- Bryan Wayne Pursey, a resident of Washington, suffered from bipolar disorder and panic disorder. His physician prescribed Neurontin, and on May 30, 1999, he committed suicide. (Docket No. 1204.)

- Tommy G. Roberson, a citizen of North Carolina, suffered from restless leg syndrome and pain. His physician prescribed Neurontin and on August 27, 2003, he committed suicide. (Docket No. 1206.)

- Steven Bentley, a resident of California, suffered from bipolar disorder and depression. His doctor, Dr. Lakshman Rasiah, prescribed Neurontin and on August 12, 2002, Bentley committed suicide. (Docket No. 1207.)

- Jacqueline Ford, a resident of Pennsylvania, suffered from pain. She was prescribed Neurontin, and on April 26, 2000, she committed suicide. (Docket No. 1210.)

In addition to alleging a fraudulent marketing campaign, each plaintiff alleges "upon information and belief" that the treating physicians prescribed Neurontin "in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin as being safe and effective for the treatment" of his disease. See e.g., Woolum Amended Complaint ("Woolum Am. Compl.") ¶ 123. Five complaints allege, upon information and belief, that the prescriber "heard directly or

otherwise learned indirectly of the statements" by defendants' Senior Medical Director Dr. Clarey on NPR stating that there was no evidence Neurontin "has been associated with suicidal behavior or that it can cause suicidal behavior." Id. at ¶ 249.⁵

In addition to alleging affirmative misrepresentations about the safety and efficacy of Neurontin for the off-label uses, plaintiffs allege that defendants fraudulently concealed and suppressed information about the effects of Neurontin on depression and suicidality. Plaintiffs contend that Neurontin causes the reduction of certain monoamines, neurotransmitters in the brain, such as serotonin. A reduction in these monoamines is associated with mood and behavioral disturbances, including depression and suicidality. (Woolum Am. Compl. ¶ 256; McGee Amended Complaint ("McGee Am. Compl.") ¶ 260.) The treating physicians testified that when deciding whether to prescribe Neurontin, they would have wanted to know the link between Neurontin and psychobiologic adverse events, e.g., depression and suicidality, or the drug's effect on reducing serotonin and other monoamines. (Woolum Am. Compl. ¶ 120 (prescriber did not know whether Neurontin reduced or decreased the production and release of dopamine, noradrenaline, or serotonin); McGee Am. Compl. ¶ 120 (prescriber testified that she was never told by

⁵See Woolum Am. Compl. ¶¶ 248-253; Valentine Am. Compl. ¶¶ 258-263; Roberson Am. Compl. ¶¶ 259-264; Smith Am. Compl. ¶¶ 284-289; and Bulger Am. Compl. ¶¶ 270-275.

defendants that Neurontin decreases the flow of serotonin or norepinephrine and that if she had known that, she would like to have known the clinical data); Roberson Amended Complaint ("Roberson Am. Compl.") ¶ 120 (prescriber testified that he prescribed Paxil for plaintiff's decedent to increase serotonin amount and stated clinical evidence indicating that Neurontin decreases amount of serotonin in the brain would be important to know before making either prescription).

2. Allegations of Direct Contacts Between Pfizer Sales Team and Prescribing Physicians⁶

Five complaints allege that Pfizer directly marketed Neurontin for off-label uses to prescribing physicians. Their specific allegations follow.

a. Valentine Amended Complaint

Plaintiff Deborah Valentine is a resident of Florida. Psychiatrist Bernard Arias and his Advanced Registered Nurse Practitioner prescribed Neurontin for her pain prior to her suicide attempt. (Docket No. 1205 ("Valentine Am. Compl.") ¶¶ 117, 133.) Plaintiff alleges that her physician prescribed Neurontin to treat her pain "in reliance upon defendants' direct and indirect advertising, marketing and promoting of Neurontin as

⁶ In a post-hearing submission, plaintiffs claim they recently discovered information of direct contacts between the Pfizer sales team and prescribing physicians in the Woolum, McGee, Vercillo, Pursey, Roberson, Bentley, and Dixon amended complaints. (Docket No. 1481 2-4.) If so, the analysis in this section would apply to those seven complaints as well.

being safe and effective for the treatment of pain.” Id. at ¶ 133.

A Pfizer sales representative detailed and promoted Neurontin for off-label, unapproved uses during a detail with her psychiatrist on at least three occasions, March 23, 2000, July 12, 2000, and July 21, 2000, and with the nurse on at least one occasion, November 11, 2002. Id. at ¶ 119-120. Dr. Arias was told by defendants’ sales representative “‘hush-hush’ and ‘off-the-record’ that Neurontin was safe and effective for indications not approved by the FDA.” Id. at ¶ 126. Dr. Arias testified that “probably a couple of times” that more than one drug representative detailed Neurontin off-label uses to him “off the record.” Id. at ¶ 127. Defendants never informed him that Neurontin was associated with suicidal behavior, mood or behavioral disturbances but that factual data on an association of the drug with suicidal behavior would have “absolutely” affected his prescribing practices. Id. at ¶ 1. Additionally, a sales representative promoted Neurontin for off-label, unapproved uses, to other healthcare providers in the same office practice as Valentine’s psychiatrist. Id. at ¶¶ 122-23.

b. Shearer Amended Complaint

Plaintiff’s decedent, Hartley Parker Shearer, was a resident of Massachusetts. As prescribed by his physician, Shearer purchased and consumed Neurontin to control the effects of

paralysis. (Docket No. 1208 ("Shearer Am. Compl.") at ¶ 129.) Shearer committed suicide on February 7, 2002. Id. at ¶¶ 3-4.

Paresh Desai, a Sales Representative for the defendants, detailed Shearer's physician, Daniel Sullivan, on March 3, 1995 for uses not approved by the FDA. Id. at ¶ 121. The sales representative did not inform Dr. Sullivan of the adverse effects of Neurontin and its association with suicidal behavior. Id.

Defendants' sales representative also detailed another one of Shearer's doctors, Dr. Keith Edwards, on multiple occasions. Warner Lambert sponsored and provided funding to Dr. Edwards, and listed him as an investigator for defendants' research regarding the off-label use of Neurontin in "Double-Blind, Placebo-Controlled, Trial of Gabapentin for the Treatment of Painful Diabetic Peripheral Neuropathy." Id. at ¶ 120. Shearer alleges Warner Lambert "directly influenced" plaintiff's prescriber, Dr. Edwards' Neurontin's prescribing practices. Id.

c. Bulger Amended Complaint

Susan Bulger, a resident of Massachusetts, was diagnosed with chronic pain and depression. (Docket No. 1211 ("Bulger Am. Compl.") ¶¶ 2, 126.) She committed suicide on August 4, 2004. Id. at ¶ 131.

Prior to plaintiff's decedent's suicide, plaintiff alleges upon information and belief that "on any of the following occasions, 1/8/04, 2/4/04, 4/1/04, 4/27/04," defendants' sales

representative detailed and promoted Neurontin for off-label, unapproved uses, to plaintiff's prescriber, Richard Goldman, M.D. Id. at ¶ 121.

d. Owens Amended Complaint

Joseph Frank Owens, a resident of Alabama, suffered from pain. (Docket No. 1212 ("Owens Am. Compl.") ¶ 2.) His physician, Dr. William Crotwell, an orthopaedist, prescribed Neurontin for the treatment of his pain. Owens committed suicide on November 9, 2002. Id. at ¶ 33. Plaintiff alleges that Dr. Crotwell was "directly influenced to prescribe Neurontin" for off-label uses to patients by defendants' paid consultant Dr. William Shepherd Fleet. Id. at ¶¶ 157-59. In addition, defendants' sales representative employee or Territory Manager John Sansom detailed Dr. Crotwell on Neurontin on approximately two dozen occasions. Id. at ¶ 160. Owens alleges, upon information and belief, that Dr. Crotwell was influenced to prescribe Neurontin for off-label uses by defendants' sales representative. Id. at ¶ 162.

e. Smith Amended Complaint

Plaintiff's decedent, Richard Smith, was a resident of Tennessee. (Docket No. 1209 ("Smith Am. Compl.") ¶¶ 1-2.) On May 13, 2004, he committed suicide. Id. at ¶ 149. Smith's doctors had prescribed Neurontin for his pain. Plaintiff alleges

that the consumption of Neurontin contributed to his injuries and death. Id. at ¶ 150. Pfizer's sales representative detailed Smith's prescriber, Paul McCombs, III, M.D., a neurological surgeon, three times on the drug Neurontin. Id. at ¶ 130. Sales representatives detailed Smith's doctors or the doctors in his medical practice on approximately 300 occasions regarding Neurontin. Id. at ¶ 131. During those occasions, defendants' sales representative or "Territory Manager" promoted unapproved uses for Neurontin to Dr. McCombs, the nurse and the other doctors. Sales representatives detailed Pamela Krancer, an Advanced Practice Nurse who prescribed Neurontin for Smith, on approximately twenty-seven occasions with respect to Neurontin. "Dr. McCombs and the members of his practice were not epileptogists or neurologists with patients for whom they would prescribe Neurontin for approved uses." Id. at ¶ 133. In addition, Pfizer detailed Smith's orthopedic doctor or the doctors in his practice 69 times. Id. at ¶ 135.

III. DISCUSSION

A. Motion to Dismiss Standard

In order to survive a motion to dismiss, "a complaint must allege 'a plausible entitlement to relief.'" Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95 (1st Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007)). In considering a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), courts must take as true the allegations in the plaintiff's pleadings and must make all reasonable inferences in favor of the plaintiff. Rivera v. Rhode Island, 402 F.3d 27, 33 (1st Cir. 2005). Nevertheless, conclusory allegations are not sufficient. Doyle v. Hasbro, 103 F.3d 186, 194-95 (1st Cir. 2007). "The court need not accept a plaintiff's assertion that a factual allegation satisfies an element of a claim, however, nor must a court infer from the assertion of a legal conclusion that factual allegations could be made that would justify drawing such a conclusion." Cordero-Hernandez v. Hernandez-Ballesteros, 449 F.3d 240, 244 n.3 (1st Cir. 2006).

Fed. R. Civ. P. 9(b) provides, "[I]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fraud claims have a heightened pleading standard which is "satisfied by an averment 'of the who, what, where, and when of the allegedly false or fraudulent

representation.'" Rodi v. S. New England Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004) (quoting Alternative Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004)).

Rule 9(b) requires that a plaintiff's averments of fraud specify the time, place, and content of the alleged false or fraudulent representations . . . The purpose of this requirement is to 'give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery.'

United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 226 (1st Cir. 2004) (quoting Doyle, 103 F.3d at 194). The heightened pleading standard of Rule 9(b) also applies to state law fraud claims that are brought in federal court. Id. at 731 n.8.

Subject to Fed. R. Civ. P. 9(b) pleading particularity requirements, plaintiffs may be allowed to plead fraud claims on information and belief. Id. at 228-229. Plaintiffs may plead upon information and belief where facts of alleged fraud "are peculiarly within the perpetrator's knowledge." Gublo v. NovaCare, Inc., 62 F. Supp. 2d 347, 356 (D. Mass. 1999) (Stearns, J.) (quoting United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997)). "Whatever further detail might otherwise be demanded is not required in these cases in which the reliance was incurred principally by third parties (the doctors), rather than by plaintiffs

themselves, and in which the representations are alleged to have occurred over a period of several years." In re Lilly & Co. Prozac Prods. Liab. Litig., 789 F. Supp. 1448, 1457 (S.D. Ind. 1992) .

Nevertheless, "[t]he requirement that supporting facts be pleaded applies even when the fraud relates to matters peculiarly within the knowledge of the opposing party." Wayne Inv., Inc. v. Gulf Oil Corp., 739 F.2d 11, 14 (1st Cir. 1984). Allegations made upon information and belief are still subject to the Fed. R. Civ. P. 9(b) particularity requirements that a complaint "set[] forth the facts on which the belief is founded." Karvelas, 60 F.3d at 226 (quoting New England Data Servs., Inc. v. Becher, 829 F.2d 286, 288 (1st Cir. 1987)). "Even where allegations are based on information and belief, supporting facts on which the belief is founded must be set forth in the complaint." Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir. 1985).

B. The Duty to Disclose

In making out their fraud claims, plaintiffs' primary contention is that defendants suppressed, concealed and failed to disclose to doctors and patients material information about the adverse psychobiologic effects of Neurontin, most significantly that it may worsen depression and lead to suicide. See, e.g., Woolum Am. Compl. ¶¶ 199-204. They also contend that Pfizer should have disclosed the "mechanism of action" of the drug so

that the prescribing physicians could perform a risk-benefit analysis for prescribing Neurontin and monitoring its results. See Woolum Am. Compl. ¶¶ 254-60. Plaintiffs allege that Pfizer had specific knowledge that Neurontin may contribute to depression and suicidality from clinical studies and trials conducted as part of its New Drug Application in 1992. Id. at ¶¶ 218. Plaintiffs assert their prescribing physicians and they, or their decedents, relied on defendants' fraudulent misrepresentations which suppressed, omitted, and concealed information about the safety and efficacy of Neurontin. Id. at ¶¶ 261, 267.

In multi-district litigation, the court must apply the law of the transferor forum, the law of the state in which the action was filed, including the transferor forum's choice-of-law rules. See Ferens v. John Deere Co., 494 U.S. 516, 523 (1990). The plaintiffs in the pilot cases brought their actions in Florida, Texas, New York, Washington, North Carolina, California, Massachusetts, Tennessee, Pennsylvania, and Alabama. Neither party contends that there are material differences in the laws of these states for purposes of resolving this dispute.

To assert a claim of common law fraud, plaintiffs must allege injury resulting from a justifiable reliance on defendants' misrepresentation.

One who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing

another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused to him by his justifiable reliance upon the misrepresentation.

Restatement (Second) of Torts § 525 (1977). "At common law, misrepresentation made for the purpose of inducing reliance by one party upon the false statement is fraudulent." Chiarella v. United States, 445 U.S. 222, 227-228 (1980). "[T]here can be no actionable claim of fraud for failure to disclose in the absence of a duty to disclose." Royal Bus. Group, Inc. v. Realist, Inc., 933 F.2d 1056, 1064 (1st Cir. 1991) (construing Massachusetts and Delaware law).⁷ See TVT Records v. Island Def Jam Music Group, 412 F.3d 82, 90-91 (2d Cir. 2005) (the requisite elements for

⁷ See also Dorsey v. Portfolio Equities, Inc., 540 F.3d 333, 341 (5th Cir. 2008) (Under Texas law, "for there to be actionable nondisclosure fraud, there must be a duty to disclose.") (internal citation omitted); Platt Elec. Supply, Inc. v. EOFF Elec., Inc., 522 F.3d 1049, 1059 n.3 (9th Cir. 2008) ("[W]here material facts are known to one party and not to the other, failure to disclose them is not actionable fraud unless there is some relationship between the parties which gives rise to a duty to disclose such known facts . . .") (internal citation omitted) (emphasis in original); Remington Rand Corp. v. Amsterdam-Rotterdam Bank, N.V., 68 F.3d 1478, 1483 (2d Cir. 1995) (Under New York law, "a concealment of facts supports a cause of action for fraud only if the non-disclosing party has a duty to disclose"); Artec Group, Inc. v. Chugach Mgmt. Servs., Inc., 470 F. Supp. 2d 1353, 1356 (M.D. Fla. 2006) ("A knowing concealment or non-disclosure of a material fact can support an action for fraud when there exists a duty to disclose the material information"). See generally Restatement (Second) of Torts § 557A (1977) ("One who by a fraudulent misrepresentation or nondisclosure of a fact that it is his duty to disclose causes physical harm to the person . . . who justifiably relies upon the misrepresentation, is subject to liability to the other").

fraudulent concealment include proof of a "failure to discharge a duty to disclose");

As a general matter, courts recognize a duty to disclose where the defendant has exclusive knowledge of material facts not known to the plaintiff. See e.g., Castleberry v. Goldome Credit Corp., 408 F.3d 773, 786 (11th Cir. 2005) ("To determine whether a common duty to disclose exists, Alabama courts evaluate, inter alia, the relationship of the parties; the relative knowledge of the parties; the plaintiff's opportunity to ascertain the undisclosed fact; and other relevant circumstances"); Haberman v. Washington Pub. Power Supply Sys., 109 Wash. 2d 107, 166-67, 744 P.2d 1032, 1069-70 (1987) ("[A]llegations of fraud may be asserted where one party to a transaction has a duty to speak because that party possesses superior knowledge yet that party fails to state, or has no basis for, an asserted material fact").⁸

⁸See also Knapp v. Neptune Towers Assocs., 72 Mass. App. Ct. 502, 507, 892 N.E.2d 820, 824 (Mass. App. Ct. 2008) ("tort of nondisclosure arises in a limited number of circumstances" including where speaker knows additional information is necessary to prevent his partial or ambiguous statement from being misleading); Wilson v. Dryvit Sys., Inc., 206 F. Supp. 2d 749, 756 (E.D.N.C. 2002) ("A duty to disclose material facts arises '[w]here material facts are accessible to the vendor only, and he knows them not to be within the reach of the diligent attention, observation and judgment of the purchaser.'") (quoting Everts v. Parkinson, 147 N.C. App. 315, 555 S.E.2d 667, 674 (N.C. Ct. App. 2001) (internal citations omitted)); Karoutas v. HomeFed Bank, 232 Cal. App. 3d 767, 771, 283 Cal. Rptr. 809, 811 (Cal. App. 1 Dist. 1991) ("In the absence of a fiduciary or confidential relationship, a duty to disclose arises at common law if material

The Supreme Court has recently recognized that "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." Wyeth v. Levine, 129 S.Ct. 1187, 1202 (2009) (holding that the FDA's drug labeling regulations do not preempt state law tort suits). "After the FDA approves a drug, the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug." Id. at 1219. See generally 21 CFR § 314.80 (placing responsibility for post-marketing surveillance on the manufacturer).

In the products liability area, courts have routinely held that a manufacturer of a drug has a duty to warn physicians, and in some cases, warn patients, about the dangers of the administration of a drug. See, e.g., Martin v. Hacker, 83 N.Y.2d 1, 8, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("The manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist . . ."); MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 138-39, 475 N.E.2d 65, 70 (1985) (holding that oral contraceptive manufacturers may not rely on warnings to the medical profession to satisfy common law duty to warn and have the duty to provide to the consumer "written warnings conveying

facts are known only to the defendant and the defendant knows that the plaintiff does not know or cannot reasonably discover the undisclosed facts.").

reasonable notice of the nature, gravity and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician or other doctor of any such information or concern to the consumer."); Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1526 (D. Minn. 1989) (upholding a jury verdict that a manufacturer fraudulently concealed significance of risk of pelvic infection in a physician package insert regarding safety of a medical device).

Some courts have further held that pharmaceutical companies have an ongoing post-sale duty to disclose information about the safety of their products. See e.g., Burton v. R.J. Reynolds Tobacco Co., 397 F.3d 906, 912 (10th Cir. 2005) (holding, under Kansas state law, that ethical drug and device manufacturers, such as pharmaceutical companies, "owe a continuing, post-sale duty to warn of product dangers, whereas manufacturers of other products generally owe a duty to warn of product dangers only at the time of sale").

Pharmaceutical drug consumers who are injured by a manufacturer's fraudulent misrepresentation or omission may have an actionable claim of fraud under some state laws. See e.g., MacDonald, 394 Mass. at 138-39, 475 N.E.2d at 70 (drug manufacturer had duty to provide consumer written warnings). Moreover, a consumer injured by a fraudulent misrepresentation to his doctor has a claim based on third party reliance. "[T]here is no general common-law principle holding that a fraudulent

misrepresentation can cause legal injury only to those who rely on it.” Bridge v. Phoenix Bond & Indem. Co., 128 S. Ct. 2131, 2143 (2008) (relying on a long line of cases “where courts have permitted a plaintiff directly injured by a fraudulent misrepresentation to recover even though it was a third party, and not the plaintiff, who relied on the defendant’s misrepresentation”).

Based on the reasoning of this caselaw, the Court concludes that a manufacturer of a pharmaceutical has a duty to disclose to physicians and patients material facts about the risks of the drug, particularly when it is engaged in off-label marketing for uses not approved by the FDA, if it knows that the plaintiff and/or his prescriber does not know or cannot reasonably discover the undisclosed facts.

C. The Contentions

Plaintiffs contend that defendants had a duty to disclose that the drug had an association with adverse psychobiologic effects, such as depression and suicidality.⁹ In their view, Pfizer fraudulently breached its duty to disclose in three respects: (1) in its national advertising campaign; (2) in its details to doctors’ offices; and (3) in its labeling and package inserts.

⁹The Court has recently rejected a Daubert challenge mounted by defendants to the plaintiffs’ experts testimony on general causation. See Memorandum and Order dated May 5, 2009 (Docket No. 1775).

1. The National Advertising Campaign

In seven complaints (Woolum, McGee, Vercillo, Pursey, Roberson, Bentley, Dixon), plaintiffs fail to allege the connection, if any, between the physician's decision to use Neurontin as a treatment for an off-label use with the extensive marketing or advertising campaigns alleged in the common allegations section (i.e., the conferences, consulting fees, publications).¹⁰ For instance, these seven plaintiffs do not claim that their prescribing physicians attended a conference where off-label uses were discussed, were detailed by defendants' sales representatives, or read a scientific article that influenced their prescription of the drug. Despite the opportunity for discovery, no doctor in these seven complaints testified she heard any misrepresentations from the Pfizer sales team or Dr. Clarey on NPR.

In an attempt to salvage these claims, plaintiffs argue that defendants' off-label marketing efforts were so pervasive that even doctors who were not contacted directly by defendants were influenced in their prescription habits by the marketing

¹⁰In plaintiffs' Post-Hearing Memorandum Regarding Defendants' Motion to Dismiss Plaintiffs' Fraud Causes of Action, they assert that they "have unearthed" additional information about sales representatives' detailing plaintiffs' prescribing physicians. (Docket No. 1481 at 2.) Plaintiffs maintain they were unable to include this data in their amended complaints and seek permission from the Court to replead these seven complaints: Woolum, McGee, Vercillo, Pursey, Roberson, Bentley, and Dixon. Id. at 2-4.

campaign's misrepresentations about Neurontin's safety and effectiveness for off-label uses. They state, "The inability to prove that Warner-Lambert or Pfizer contacted a doctor directly does not mean that that doctor was not influenced by Warner-Lambert and Pfizer marketing efforts." Woolum Am. Compl.

¶ 235. Plaintiffs allege that any doctor who prescribed Neurontin, even without direct contact with defendants was "most likely influenced" in her prescribing habits by a doctor who was in contact with defendants: "Doctors work in an environment where informal communications among fellow doctors, or 'word-of-mouth,' play an important role in the dissemination of information about drugs and treatments." Id. at ¶ 237.

Defendants contend that in making this argument, the plaintiffs are essentially advocating a "fraud on the market theory" as a proxy for the proof of actual reliance required under common law. In securities fraud litigation, the fraud on the market theory creates "a rebuttable presumption of reliance" because an "investor who buys or sells stock at the price set by the market does so in reliance on the integrity of that price." Basic Inc. v. Levinson, 485 U.S. 224, 249, 247 (1988). The Supreme Court reasoned that the rebuttable presumption is also "supported by common sense and probability" because empirical studies have tended to confirm Congress' premise that the market price of shares traded on well-developed markets reflects all

publicly available information, and, hence, any material misrepresentations." Id. at 246.

However, "no court has ever adopted a 'fraud on the market' type theory outside the securities fraud context, and the majority of courts which have had occasion to extend the theory to common law fraud cases have expressly declined to do so." Coleman v. Danek Med., Inc., 43 F. Supp. 2d 629, 635 n. 4 (S.D. Miss. 1998); see also In re Ford Motor Co. Vehicle Paint Litig., 182 F.R.D. 214, 221 (E.D. La. 1998) ("[T]he vast majority of states have never adopted a rule allowing reliance to be presumed in common law fraud cases, and some states have expressly rejected such a proposition"). In McLaughlin v. American Tobacco Co., 522 F.3d 215, 223 (2d Cir. 2008), the Second Circuit recently rejected a similar argument that defendants' marketing campaign created a rebuttable presumption that class members purchased defendants' cigarette products in reliance on misrepresentations in the campaign. It held that the court could not assume that the cigarette market "internalized the misrepresentation to such an extent that all plaintiffs can be said to have relied on it." Id. at 224. See also Chudasama v. Mazda Motor Corp., 123 F.3d 1353, 1369, n.39 (11th Cir. 1997) ("The fraud on the market theory of securities law, however, is based on concepts and policies that simply do not apply in a products liability case.").

Undoubtedly, word-of-mouth plays an important role in the dissemination of drug information. Notwithstanding the alleged pervasive promotions, the prescription drug industry is too dissimilar from the securities market to support applying a "fraud on the market" theory to establish a rebuttable presumption that physicians relied on a national drug marketing campaign. See Prohias v. Pfizer, Inc., 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007) ("[T]here is no prescription drug 'market' at least as that term is understood in the securities context"). Accordingly, the Court allows the motion to dismiss all fraud claims alleging affirmative misrepresentations or a suppression of information as part of a national marketing campaign because there is no allegation of reliance on specific statements or misrepresentations.

2. Details, Details

A different question arises with respect to those complaints where plaintiffs allege that Pfizer actively detailed the doctors or the doctors' offices. The Valentine complaint alleges that on multiple occasions, the sales representative promoted Neurontin as "good" for off-label uses. (Docket No. 1205 at ¶ 127.) This complaint meets the strictures of Rule 9(b) by alleging the affirmative misrepresentation with particularity. None of the remaining complaints, however, contain comparable allegations of specific affirmative misrepresentations made by sales

representatives to prescribing physicians upon which the doctors relied. Since plaintiffs had the opportunity to conduct discovery, amended complaint allegations about affirmative misrepresentations based solely on information and belief are inappropriate.

Raising a theory of fraudulent suppression, plaintiffs respond that defendants had a duty to disclose the depressive and suicidal side effects of Neurontin when they knew that over 90 percent of the use would be off-label. Plaintiffs' argument is persuasive. Not only did the sales people allegedly detail the offices and provide samples without disclosure of the risks, but defendants allegedly failed to disclose the risks of its drugs in the product labeling itself. See e.g., Woolum Am. Comp. at ¶ 257.

Pfizer argues that the fraudulent concealment claims should be dismissed as duplicative of plaintiffs' failure to warn claims. They argue that the only "duty to disclose" alluded to by the amended complaints is "the duty of a manufacturer to warn of a non-obvious risk associated with the normal use of its product about which the manufacturer knows or has reason to know -- i.e., the same duty that underpins plaintiff's strict liability claims." (Docket No. 1233 at 6 n.3.)

Under some state laws, claims based on a manufacturer's failure to warn may be brought as either strict liability or

negligence actions, or both. Anderson v. Owens-Corning Fiberglas Corp., 53 Cal. 3d 987, 1003, 810 P.2d 549, 559 (1991)

(manufacturer may escape negligence liability if it reasonably decided risk of harm was such as to not require a warning but may be strictly liable if it "failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product"); Bukowski v. CooperVision Inc., 185 A.D.2d 31, 33, 592 N.Y.S.2d 807, 808 (N.Y.A.D. 3d 1993) ("It is well settled that a plaintiff may recover in strict products liability or negligence for a manufacturer's failure to warn of the risks and dangers associated with the use of its product"). In other states, failure to warn claims based on pharmaceutical drugs may only be brought as negligence actions. See Hahn v. Richter, 543 Pa. 558, 563, 673 A.2d 888, 891 (1996) ("[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability.") See generally Restatement (Second) of Torts § 388 (1965).

In contrast to failure to warn claims, though, claims based on a fraudulent concealment or misrepresentation require scienter. A fraud claim generally requires plaintiff to establish that defendant made a false representation which was

knowingly "false or was recklessly indifferent to its truth or falsity," with the intention to defraud, upon which plaintiff justifiably relied and incurred damages. Pinney v. Nokia, Inc., 402 F.3d 430, 444 (4th Cir. 2005). "Concealment of a material fact, with intent to deceive, satisfies the false representation element of fraud." Id. at 445.

It is true that in some circumstances and under some state laws, courts have concluded that "failure to warn" and fraudulent concealment claims are duplicative. See e.g., Waterhouse v. R.J. Reynolds Tobacco Co., 270 F. Supp. 2d 678, 684-85 (D. Md. 2003) (holding the plaintiff's claim for fraudulent concealment was "in large part nothing more than a failure-to-warn claim in different dress" and dismissing it as duplicative); Hamner v. BMY Combat Sys., 869 F. Supp. 888, 893 (D. Kan. 1994)) (dismissing plaintiff's fraudulent concealment theory, the basis of which is "properly stated as a claim for a breach of defendants' duty to warn"); Spangler v. Sears, Roebuck & Co., 759 F. Supp. 1337, 1338 (S.D. Ind. 1991) (holding fraudulent concealment and failure to warn claims are duplicative where plaintiff alleges drug manufacturer fraudulently misrepresented that smoking cessation drug was safe and fraudulently concealed knowledge of the drug's dangers); Kline v. Pfizer, Inc., No. 08-3238, 2009 WL 32477, at *4 (E.D. Pa. Jan. 6, 2009) ("very crux of [fraudulent concealment] claims rests on a failure to warn theory of

liability"). Nonetheless, other courts have concluded that the claims were not duplicative. See e.g., Burton v. RJ Reynolds Tobacco Co., 916 F. Supp. 1102, 1104-05 (D. Kan. 1999) (distinguishing Hamner, and holding that a fraudulent concealment claim is not duplicative where defendants allegedly withheld medical and scientific data indicating product hazards from the public by concealing the information from the medical community and consumers). The caselaw does not always draw clear lines.

In the circumstances of this case, plaintiffs allege the elements necessary to establish a claim of fraudulent concealment, namely that defendants intentionally withheld material information about the side effects of Neurontin from both consumers and their prescribing physicians, with the intent to deceive.

For the above reasons, the motions to dismiss the fraudulent concealment claims are DENIED.

IV. ORDER

The motions to dismiss the fraud claims are ALLOWED with respect to all claims of affirmative fraudulent misrepresentations with the exception of claim of fraud in the Valentine Complaint. The motions to dismiss the fraudulent concealment claims are DENIED in all the complaints except to the extent they are premised on the claim of fraudulent omissions in the national advertising and marketing campaign.

S/PATTI B. SARIS

United States District Judge

Publisher Information

**Note* This page is not part of the opinion as entered by the court.
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 Pfizer, Inc. (Defendant)
 Warner-Lambert Company (Defendant)
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James M. Harpring (Consolidated Plaintiff)
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Pfizer, Inc. (Defendant)
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